

6.0 What is Claimed is:

- 1 1. At least one implant consisting substantially of cortical bone, said implant
2 comprising a canal surrounded by a continuous or discontinuous wall of cortical bone in the
3 shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant having a top
4 face and a bottom face, each of which is substantially planar, with said planes being substantially
5 parallel to each other.
- 1 2. The implant of claim 1 consisting substantially of cortical bone, said implant
2 comprising a canal surrounded by convexly curved anterior cortical bone face and three
3 substantially rectilinear cortical bone faces unitary with said convexly curved anterior cortical
4 bone face.
- 1 3. The implant of claim 2 which has a substantially "D"-shaped external profile.
- 1 4. The implant of claim 2 wherein said canal has a substantially "D"-shape.
- 1 5. The implant of claim 2 further having an external feature on said top face, said
2 bottom face or both.
- 1 6. The implant of claim 5 wherein said external feature is at least one groove or
2 tooth.
- 1 7. The implant of claim 6 wherein said external feature is a series of teeth which
2 angle toward said convexly curved anterior face.
- 1 8. The implant of claim 1 wherein an osteogenic, osteoinductive or osteoconductive
2 composition is packed within said canal.
- 1 9. The implant of claim 8 wherein said osteogenic, osteoinductive or
2 osteoconductive composition derives from the intervertebral space into which said implant is

FOUO-EEF0260

-25-

3 inserted, is hydroxyapatite, bone powder, bone product, bone morphogenetic protein, bioactive
4 glass, bioactive ceramic, or combinations of these.

1 10. The at least one implant of claim 1 comprising discontinuous walls consisting
2 substantially of cortical bone, wherein said discontinuous walls are mirror image halves which, in
3 combination, form said shape.

1 11. The at least one implant of claim 1 comprising stacked implants consisting
2 substantially of cortical bone, said implants comprising a canal surrounded by a continuous or
3 discontinuous wall of cortical bone in the shape of a circle, an ellipse, or an asymmetric shape,
4 thereby forming a stacked implant having a top face and a bottom face, each of which is
5 substantially planar, with said planes being substantially parallel to each other.

1 12. The at least one implant of claim 11 wherein said stacked implants are pinned to
2 each other.

1 13. An implant consisting substantially of at least two shaped cortical bone implants
2 stacked on top of or adjacent to each other.

1 14. The implant of claim 13 wherein said shaped cortical bone implants are adapted to
2 form a unitary implant for implantation into an appropriately dimensioned cavity formed between
3 adjacent vertebrae.

1 15. The implant of claim 14 wherein said cortical bone implants are pinned to each
2 other by cortical bone pins, pins consisting of biocompatible synthetic material or metallic pins.

100280-226102001

1 21. The method of claim 20 wherein said asymmetric shape is substantially “D”-
2 shaped.

1 27. The method of claim 17 which further comprises machining an external feature
2 into the top the bottom or both surfaces of the implant.

1 28. The method of claim 27 wherein said external feature is machined by passing said
2 implant through a broach or by repeatedly passing said implant over a plurality of cutting teeth.

1 29. The method of claim 26 which further comprises machining an external feature
2 into the top the bottom or both surfaces of the implant.

1 30. The method of claim 27 wherein said external feature is machined by passing said
2 implant through a broach or by repeatedly passing said implant over a plurality of cutting teeth.

1 31. A broach for forming a canal of desired shape in bone which comprises a plurality
2 of spaced apart rings, wherein the profile of said plurality of spaced apart rings tapers from a first
3 circular ring to a final ring having said desired shape, said taper allowing for removal by each
4 consecutive ring of no more than about 0.004" of bone.

1 32. An apparatus for forming the external profile of a bone plug having an
2 asymmetric canal, said apparatus comprising (a) a spindle mounted on (b) an asymmetric cam,
3 wherein the shape of said spindle matches the shape of the asymmetric canal of said bone plug so
4 as to allow for a tight mounting of said bone plug onto said spindle, and wherein said asymmetric
5 cam is biased toward (c) a cam follower such that said spindle mounted bone plug is made to
6 contact (d) a cutter means to an extent dictated by the contact of the cam and cam follower such
7 that said cutter fashions an external profile onto the bone plug dictated by the shape of said
8 asymmetric cam.

1 33. The apparatus of claim 32 comprising:

2 (a) a cross-slide housing a shaft connected to said spindle, to which is also affixed said
3 asymmetric cam;

4 (b) a carriage having a slide-way in which said cross-slide translates in a first, Y-plane,
5 said carriage being slideably mounted on a bed such that said carriage translates in a
6 second, X-plane, transverse to said Y-plane;

7 (c) a cam-follower which limits the translation of said cross-slide in said Y-plane as said
8 asymmetric cam contacts said cam-follower; and

100230 FEB 10 1999

37. An apparatus for forming the external profile of a bone plug having an asymmetric canal, said apparatus comprising (a) a spindle, wherein the shape of said spindle matches the shape of said asymmetric canal of said bone plug so as to allow for a tight mounting of said bone plug onto said spindle, and (b) an asymmetrically shaped grinder wheel which may be brought into contact with said bone plug mounted on said spindle, wherein said grinder wheel and said spindle are maintained in registered contact with each other via a gear such that the rate at which the bone plug rotates in relation to the rate of the rotation of the grinder wheel differs sufficiently to allow abrasion of the surface of the bone plug so as to form an external profile thereon which is dictated by the asymmetry of said grinder wheel.

-30-

1 38. A method for inducing fusion of cervical vertebrae which comprises removing a
2 portion of the intervertebral disc between the adjacent vertebrae that are to be fused, and
3 inserting into said space at least one implant consisting substantially of cortical bone, said
4 implant comprising a canal surrounded by a continuous or discontinuous wall of cortical bone in
5 the shape of a circle, an ellipse, or an asymmetric shape, thereby forming an implant having a top
6 face and a bottom face, each of which is substantially planar, with said planes being substantially
7 parallel to each other.

1 39. The method of claim 38 wherein said canal is surrounded by a convexly curved
2 anterior cortical bone face and three substantially rectilinear cortical bone faces unitary with said
3 convexly curved anterior cortical bone face, thereby forming an implant having a top face and a
4 bottom face.

1 40. The method of claim 39 wherein said canal is packed with osteogenic,
2 osteoinductive or osteoconductive material.

1 41. An implant consisting substantially of cortical bone, said implant having been
2 prepared by a process comprising:

- 3 (a) obtaining a plug of bone consisting substantially of cortical bone by using a core
4 cutter having a central drill bit, thereby forming a canal through the bone plug
5 obtained with the core cutter;
6 (b) machining the bone plug of step (a) to produce a "washer-shaped" bone plug;
7 (c) machining the canal through the bone plug to form an asymmetric shape therein; and
8 (d) using said asymmetric shape to machine an outside profile of the bone plug.

1 42. The implant of claim 41 wherein said plug of bone is obtained by cutting into the
2 diaphysis of a long bone and into the intramedullary canal of said long bone to form a bone plug
3 having a substantially cortical end and an end derived from the wall of the intramedullary canal.

1 43. The implant of claim 42 wherein the end of the plug of bone derived from the
2 intramedullary canal is machined to form a substantially planar surface to obtain a substantially
3 "washer-shaped" bone plug composed substantially of cortical bone.

T00260-EEB70460

50. An implant prepared by a process comprising:

- (a) cutting a segment of cortical bone;
- (b) shaping said segment of cortical bone into a symmetric half of the final shape of said implant comprising a canal surrounded by a continuous or discontinuous wall of cortical bone, such that when implanted in juxtaposition with a mirror image segment, an implant is formed having a circular, an elliptical, or an asymmetric shape, a top face and a bottom face, each of which is substantially planar, with said planes being substantially parallel to each other; and
- (c) cutting appropriate lengths of said shaped segment of cortical bone such that said cut length provides half of an implant having a desired height.

1 51. The implant of claim 50 which further comprises machining an external feature
2 into the top the bottom or both surfaces of the implant.

1 52. The implant of claim 41 which further comprises machining an external feature
2 into the top the bottom or both surfaces of the implant.

1 53. An apparatus for inscribing an external feature into a bone implant which
2 comprises: (a) a base having a recess, said recess housing (b) a plurality of cutting blades having
3 both a non-cutting upper surface, against which said bone implant may be pressed, and a cutting
4 upper surface, for inscribing said external feature into said bone implant; said base providing a
5 sliding surface for a (c) carriage; said carriage being slideably fixed to said base by (d) posts
6 holding (e) a guide rod; said carriage further having a (e) tensionable slot for receiving said
7 implant which is loaded into said slot and pushed snugly against said non-cutting upper surface
8 of said plurality of cutting blades, such that said implant may then be raked across said cutting
9 surface of said plurality of blades to inscribe said external feature therein.

1 54. A method of making a substantially cortical bone implant comprising:
2 (a) removing the termini of a tibia or femur to produce a diaphysial shaft comprising a
3 natural intra-medullary canal;
4 (b) longitudinally sectioning the anterior margin of the tibia or linea aspera of the femur as
5 close to the intra-medullary canal as possible to produce a shaft of cortical bone of
6 substantially triangular cross-section;
7 (c) cutting said shaft of cortical bone into segments of desired length;
8 (d) drilling a cannulation through a long axis of said segments of cortical bone, wherein said
9 cannulation comprises a bore of such diameter as to leave at least about 2 mm of bone
10 stock between the cannulation and any external side of the cortical bone segment;
11 (e) machining an asymmetry into the cannulation to produce a key way; and
12 (f) further machining the cannulated bone segments utilizing said key way as a means for
13 gripping the cannulated bone segments to produce an implant of desired shape and size
14 characteristics.

1002280-2220460

-33-

1 55. A cortical bone implant produced by the method of claim 54.

1 56. A method of fusing adjacent vertebrae in need thereof which comprises inserting
2 into a space created between said adjacent vertebrae a cortical bone implant according to claim
3 55.

1 57. The cortical bone implant of claim 55 comprising an osteogenic, osteoinductive or
2 osteoconductive material packed within said cannulation.

1 58. The cortical bone implant of claim 57 wherein said osteogenic, osteoinductive or
2 osteoconductive material comprises a plug of cancellous bone.

100280-22610260

*add
A₁*

-33-

- 1 55. A cortical bone implant produced by the method of claim 54.
- 1 56. A method of fusing adjacent vertebrae in need thereof which comprises inserting
2 into a space created between said adjacent vertebrae a cortical bone implant according to claim
3 55.
- 1 57. The cortical bone implant of claim 55 comprising an osteogenic, osteoinductive or
2 osteoconductive material packed within said cannulation.
- 1 58. The cortical bone implant of claim 57 wherein said osteogenic, osteoinductive or
2 osteoconductive material comprises a plug of cancellous bone.
59. A method for posterior lumbar intervertebral fusion which comprises implantation between
vertebrae to be fused of an implant comprising substantially cortical bone having a substantially
crescent shape with a width, top dimension, bottom dimension, a curvature defining an inner,
concave surface and an outer, convex surface, a length and a height adapted for posterior lumbar
intervertebral fusion.
60. The method according to claim 59 wherein said implant is inserted on either side of lumbar
intervertebral spaces to thereby stabilize and assist in fusion of adjacent lumbar vertebrae by
distraction of the lumbar vertebrae, removal of an appropriate amount and shape of intervertebral
disc matter and insertion of said implant on each side on a posterior approach with said concave
surface of each said implant set to face inwardly, toward the center of the vertebral body, while
said convex surface is set to match, as much as possible, the natural external curvature of the
lumbar vertebrae.
61. A posterior lumbar intervertebral fusion implant comprising substantially cortical bone having a
substantially crescent shape with a width, top dimension, bottom dimension, a curvature defining
an inner, concave surface and an outer, convex surface, a length and a height adapted for posterior
lumbar intervertebral fusion.
62. The implant according to claim 61 wherein said implant is inserted on either side of lumbar
intervertebral spaces to thereby stabilize and assist in fusion of adjacent lumbar vertebrae by
distraction of the lumbar vertebrae, removal of an appropriate amount and shape of intervertebral
disc matter and insertion of said implant on each side on a posterior approach with said concave
surface of each said implant set to face inwardly, toward the center of the vertebral body, while
said convex surface is set to match, as much as possible, the natural external curvature of the
lumbar vertebrae.
63. A method of making a posterior lumbar intervertebral fusion implant comprising substantially
cortical bone having a substantially crescent shape with a width, top dimension, bottom
dimension, a curvature defining an inner, concave surface and an outer, convex surface, a length
and a height adapted for posterior lumbar intervertebral fusion, which comprises cutting a segment
of cortical bone, shaping said segment of cortical bone such that said implant may be inserted on
either side of lumbar intervertebral spaces to thereby stabilize and assist in fusion of adjacent
lumbar vertebrae by distraction of the lumbar vertebrae, removal of an appropriate amount and
shape of intervertebral disc matter and insertion of said implant on each side on a posterior
approach with said concave surface of each said implant set to face inwardly, toward the center of
the vertebral body, while said convex surface is set to match, as much as possible, the natural
external curvature of the lumbar vertebrae.
64. The implant according to claim 61 substantially as shown and described in figures 8d-8G.
65. A method for inducing intervertebral fusion which comprises implantation of at least one implant
according to claim 64 between adjacent vertebrae.

100280-EE6T0260